DETAILED ACTION

Applicants' arguments, filed September 11, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness

1) Claims 1, 2, 4, 11, 14, 25 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (US 5,994,329) in view of Kelly (US 4,817,819).

Applicant's Arguments

Applicant argues there is little guidance or specificity regarding dosing frequency other than less frequent daily dosing and certainly no indication that any particular dosing regimen is critical or even important for the patient. Further, it is clear that Daifoitis regards the days upon which dosing takes place is unimportant. Daifotis also discloses a kit without any specificity as to how many unit dosages of bisphosphonate

or any recommendations or suggestion regarding structure of this kit other than that it can include a card having the dosages in order of their intended use. Additionally there is no recognition or suggestion of whether the placebo or supplement should be administered concurrently with the bisphosphonate product or at a different time or day. In contrast the instant invention requires bisphosphonates to be taken on different day than the supplement. The specific arrangement of dosages as set forth in the present claims addresses the issue of proper dosing regimens that result in efficacy for their osteoporosis. In regard to Kelly, Kelly discloses administering birth control pills and do not relate to the challenges of bisphosphonate dosing. Kelly does not address the compliance issues associated with the continuous administration of a pharmaceutical active such as bisphosphonates. Thus the combination of references is not obvious.

Examiner's Response

These arguments are not persuasive. The reference discloses weekly dosing and thus gives guidance to the dosing frequency and thus encompasses the instant claims. The reference specifically states "These methods comprise orally administering to a mammal in need there of a pharmaceutically effective amount of a bisphosphonate as a unit dosage according to a continuous schedule having a dosing interval selected form the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing and twice-monthly dosing." This suggests and is guidance for one to arrive at the kits of the instant claims by disclosing a dosing interval of "once-weekly". In regard to how many

unit dosages, it is in the relative skill of one of ordinary skill in the art to determine the amount of unit dosages required for the desired therapy. Further, although Kelly discloses the main embodiment is to store birth control pill, it is used to show that it is known to arrange pharmaceutical compositions in an order that is convenient for administration in a 28 day cycle and the blister packs are labeled with the day therapy begins. Further the reference discloses that various changes and modifications can be made to the invention to adapt it to various usages and conditions (col. 5, lines 46-51), which would include those disclosed by Daifotis. It would be obvious to store the pharmaceuticals of Daifotis in blister packs labeled with the day the therapy begins or in an order and arrangement that will aid a patient in keeping track when medicine is being taken in order to insure proper administration of the pharmaceutical. It would have been obvious to use a 28 day cycle blister pack comprising 4 dosages because this size blister pack is known to be used in the art and because the days correspond more closely to the number of days in a month (28-31) than say a 21 day or 35 day blister pack. In regard to the supplement, the reference discloses the kits of the invention preferably include a number of unit dosages and such kits can include a card having the dosages oriented in the order of their intended use. The reference also discloses placebo dosages, or calcium or dietary supplements, either in a form similar to or distinct from the bisphosphonate dosages, can be included to provide a kit in which a dosage (which is interpreted as indicating one), is taken every day. Thus it is concluded that when the bisphosphonate dosage is not taken, a supplement is taken and the two are not take on the same day.

2) Claims 1, 2, 4, 11, 14, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (US 5,994,329) in view of Allendorf et al. (US 5,265,728).

Applicant's Arguments

See Applicant's arguments above in regard to Daifotis et al. In regard to Allendorf et al., the arguments for Allendorf et al. are the same as for Kelly above.

Examiner's Response

See the Examiner's response above in regard to Daifotis et al. The Examiner's response for Allendorf et al. is the same as for Kelly above. Allendorf et al. disclose a blister pack comprising 7 spaces for each day of the week. Although it discloses birth control and hormone replacement therapy, the reference is used to show the arrangement of pharmaceuticals in a blister pack that includes a memory aid to ensure proper administration of a pharmaceutical. It would have been obvious to arrange the bisphosphonates in rows comprising 7 spaces for each day of the week to ensure the medication is taken in the right order and for the appropriate amount of weeks. Further, as in the case of Kelly, Allendorf et al. also discloses the packs may be used for various usages and conditions (col. 7, lines 60-65), which would include those disclosed by Daifotis.

Claims 1, 2, 4, 11, 14, 25 and 26 are rejected.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612